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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,321	08/31/2006	Morten Reeslev	36731-000093/US	9441
30593 7590 07/14/2008 HARNESS, DICKEY & PIERCE, P.L.C. P.O. BOX 8910			EXAMINER	
			MARTIN, PAUL C	
RESTON, VA 20195			ART UNIT	PAPER NUMBER
			1657	
			MAIL DATE	DELIVERY MODE
			07/14/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)					
Office Action Comments	10/591,321	REESLEV ET AL.					
Office Action Summary	Examiner	Art Unit					
	PAUL C. MARTIN	1657					
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply							
<ul> <li>A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.</li> <li>Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.</li> <li>If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.</li> <li>Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).</li> </ul>							
Status							
1) Responsive to communication(s) filed on							
·—	<i>-</i> —						
•	71						
closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.							
Disposition of Claims							
4)⊠ Claim(s) <u>1-47</u> is/are pending in the application.	4) Claim(s) 1-47 is/are pending in the application.						
	4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.							
6) Claim(s) is/are rejected.							
7) Claim(s) is/are objected to.	· · · · · · · · · · · · · · · · · · ·						
8) Claim(s) <u>1-47</u> are subject to restriction and/or e	election requirement						
o) Claim(s) 1-41 are subject to restriction and/or e	siection requirement.						
Application Papers							
9)☐ The specification is objected to by the Examiner.							
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).							
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.							
TI) The eath of declaration is objected to by the Examiner. Note the attached Office Action of John FTO-192.							
Priority under 35 U.S.C. § 119							
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>							
Attachment(s)  1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date	4)  Interview Summary Paper No(s)/Mail Da 5)  Notice of Informal P 6)  Other:	(PTO-413) te					

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## **DETAILED ACTION**

Claims 1-47 are pending in this application.

## Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-45, drawn to a sample preparation method for a medium suspected of containing contaminants.

Group II, claim(s) 46, drawn to a kit for the determination of contaminants in a medium.

Group III, claim(s) 47, drawn to use of a closed, sterile filter device.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: PCT Rule 13.2 requires that unity of invention only exists when the shared same or corresponding technical feature is a contribution over the prior art. The inventions listed as Groups I-III doe not relate to a single general inventive concept because they lack the same or corresponding special technical feature. The "special technical feature" of Group II is either a sterile filter device or an agent capable of releasing a detectable moiety upon interaction with contaminants. Longoria (US 5,081,017) teaches a sterile (inherently or would not be enabled) filter device and Koumara *et al.* (US 4,591,554) teaches a non-fluorescent umbelliferone derivative that upon interaction with microorganisms will release a fluorescent umbelliferone derivative.

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This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Each of the genus of species are as follows:

1) contaminants (as described in claim 3)

2) liquid medium (as described in claim 5)

3) enzyme (as described in claim 15)

4) substrate (as described in claim 18)

Applicant is required, in reply to this action, to elect a single species from each of the four genus as appropriate to the elected group to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

The following claim(s) are generic: All claims are generic.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The contaminants are directed to different species of microorganisms sharing no common technical feature and having different structures, habitats and compositions, the liquid mediums are unique from one another in terms of composition and derivation, the enzymes are distinct in terms of structure and preferred substrate, and the substrates are distinct in terms of structure and chemical composition.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

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remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL C. MARTIN whose telephone number is (571)272-3348. The examiner can normally be reached on M-F 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paul Martin Examiner Art Unit 657

6/30/08 /JON P WEBER/ Supervisory Patent Examiner, Art Unit 1657